IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA **Public Version**
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	C.A. No. 19-2053-RGA **Public Version**
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, GERBERA THERAPEUTICS, INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	CA No. 22-1395-RGA Public Version

Declaration of Bharat Reddy Chintapally

1. I am an Executive Director of defendant MSN Pharmaceuticals Inc., MSN Laboratories Private Limited and MSN Life Sciences Private Limited. I have held this position since 2006.

2. As an Executive Director of MSN Laboratories, I am familiar with and responsible for Business Development, Sales & Marketing, Portfolio, Research & Development as well as Manufacturing Operations of MSN Laboratories Private Limited, including MSN Group's subsidiaries MSN Pharmaceuticals Inc. and MSN Life Sciences Private Limited

(hereinafter collectively, "MSN"). I make this declaration based on my personal knowledge of MSN's present financial condition, its practices over the 19 years I have been employed here, and my knowledge and understanding of the financial aspects of the pharmaceutical industry in general.

3. MSN's current financials as well as estimates are as below.

[redacted]

By the end of FY 23-24, [redacted].

4. We are one of the fastest growing knowledge-driven, research-oriented generic pharmaceutical companies. We were established in 2003 and we have 20 manufacturing facilities in Hyderabad, India for both active pharmaceutical ingredients (API) and final dosage forms (FDF) and one FDF manufacturing facility in Piscataway, NJ. MSN group employs around 20,000 personnel globally. We have a world class R&D center in Hyderabad housing around 2200 top-notch scientists dedicated to both API and FDF research and development. Our manufacturing facilities are approved by many global regulatory bodies including USFDA, EDQM, WHO-GENEVA, HEALTH CANADA and PMDA Japan, etc. We have around 950 national and international patent applications on file with around 180 national granted patents and around 160 granted international patents.

5. Additionally, MSN has considerable experience with recent at-risk launches for Tasimelteon and Pirfenidone, and is familiar with the planning required and the strategies behind such at-risk launches. We have one approved manufacturing facility for FDF and API each, and we plan to add one additional facility each for FDFs and APIs very soon. We have access to all generic distributors and pharmacy network in the United States to support the sale of these products.

6. I understand that Novartis, through the declaration of its financial expert Dr. Christopher Vellturo, says that MSN would not have the financial wherewithal to compensate Novartis for any damages it would allegedly suffer if MSN were to launch a generic sacubitril-valsartan ANDA product at-risk, either alone or as one of multiple generics entering the market, and then subsequently be enjoined should this Court's judgment regarding the '659 and '918 patents be reversed on appeal and MSN is found liable for infringement. For the reasons I explain below, I disagree.

7. Based on Novartis' current financial report guidance, sales of ENTRESTO® are estimated to be approximately $3.851B annually. For the period from [redacted] through December 2024, that translates to approximately $1.3B in sales. Assuming a profit margin of [redacted]), which is typical of a blockbuster drug like ENTRESTO® and for a company of Novartis' [redacted]

8. Should MSN launch its generic sacubitril-valsartan ANDA product at-risk, [redacted]

9. Using the figures above as a guide, and with MSN launching [redacted] Novartis' ENTRESTO®, which is typical of the generic industry, [redacted]

10. MSN would hold in escrow this revenue and profits until the final resolution of any appeals, and that escrowed revenue and profits would be used toward satisfying any judgment, should one be awarded to Novartis.

11. And in addition to using MSN's escrowed revenue and profits to satisfy an award of damages to Novartis, should that occur, MSN's current financial condition would allow it to cover the difference between escrowed sales and Novartis' lost profits based on available cash and reserves, and anticipated profits from sales of other products. Also, as listed in paragraph 3 above, [redacted]

12. MSN also has the ability to control and limit the amount/volume of generic sacubitril-valsartan product it manufactures and distributes in the United States, and thereby mitigate its potential financial exposure.

13. Further, MSN has the potential to acquire insurance coverage for the profit differential should the Court award Novartis damages. There are several insurance companies that cover potential losses associated with litigation risk and the MSN's potential financial exposure is well within the amounts insurance companies cover.

14. It is thus my opinion that contrary to Novartis' speculation, MSN is well positioned financially to satisfy any judgment that may later be awarded against MSN if the Court's judgment regarding any of Novartis' patents, including the '659 and '918 patents, were overturned on appeal.

15. It should be noted that MSN first began development of a generic sacubitril-valsartan product [redacted] and several research and development teams were involved in its development. At the outset, we focused on developing our own new and unique active pharmaceutical product. We spent almost two years working on the development of our crystalline Form-S sacubitril-valsartan compound and a manufacturing process that could produce commercial quantities of API consistently within our specifications. Our formulation team also was able to develop a bioequivalent tablet that successfully meet the required bioequivalency metrics. And for more than four years now, MSN has been in litigation with Novartis and addressing their Citizen Petitions filed with the FDA. All told, MSN has spent over [redacted] Additionally, MSN has taken steps to prepare for its commercial launch and it has incurred significant costs in connection with a potential launch. We have [redacted] In view of MSN's years-long investments and work in developing a successful FDA-approved sacubitril-valsartan product and its ongoing investments and incurred costs for an eventual launch, MSN believes that it would suffer considerable harm if it were enjoined from selling its product. MSN finds itself in a unique competitive position against other generic drug manufacturers and the opportunities for MSN to successfully launch its generic sacubitril-valsartan product are tremendously important to our company and its future business plans and investments in other products in our portfolio.

16. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on August 6, 2024.

Bharat Reddy Chintapally

CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2024, I caused a copy of the foregoing document(s) to be served by e-mail to the following counsel listed below.

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